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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,106	09/26/2000	PAUL R. SLEATH	VPISW002CON	5809

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EXAMINER
DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
1614	15

DATE MAILED: 04/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/670,106	SLEATH ET AL.	
	Examiner	Art Unit	
	Cybille Delacroix-Muirheid	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2002 and 20 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-25,28-32,35-38 and 41-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *20-25,28-32,35-38 and 41-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☒ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The following is responsive to Applicant's amendment received Jan. 29, 2002 and the interview summary of June 20, 2002.

Claims 26, 27, 33, 34, 39, 40, 47, 48 and 49 are cancelled without prejudice or disclaimer. No new claims are added. Claims 20-25, 28-32, 35-38, 41-46 are currently pending. Claims 1-19 are withdrawn from consideration.

The previous claims rejections under 35 USC 112, paragraph 1 and paragraph 2, set forth in paragraphs 4-5 of the office action mailed July 25, 2001 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim objection set forth in paragraph 3 of the office action mailed July 25, 2001 **is withdrawn** in view of Applicant's amendment cancelling claim 49.

The previous double patenting rejection under 35 USC 101 set forth in paragraphs 6-7 of the office action mailed July 25, 2001 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous rejection of claims 20-25 and 28-32 (previously 20-27, 28-34, 49) under the judicially created doctrine of double patenting set forth in paragraphs 8-9 in the office action mailed July 25, 2001 **is maintained** until receipt of an appropriate Terminal Disclaimer.

All claim rejections under 35 USC 102(b) set forth in paragraphs 10-14 of the office action mailed July 25, 2001 **are withdrawn** in view of Applicant's amendment and the remarks contained therein.

Information Disclosure Statement

Applicant's Information disclosure Statement received July 26, 2002 has been considered in part, i.e. US patents and foreign documents only as well as the two CAPLUS abstracts listed on page 2. Due to the number of parent applications, it is respectfully requested that Applicant indiciate which applications the remaining references may be located or if possible, Applicant shoould resubmit the remaining references.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 20-25, 28-32, 35-38, 41-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,136,787. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and USPN '787 claim a peptide compound comprising an amino acid sequence having an N-terminal blocking group and C-terminal Asp connected to an electronegative leaving group, wherein the amino acid sequence substantially corresponds to at least a portion of the sequence Ala-Tyr-Val-His-Asp, residues 112-116 of SEQ ID NO:3. Furthermore, both the instant application and USPN '787 claim pharmaceutical compositions of said compounds as well as methods of using said compounds to inhibit IL-1β protease activity, to treat inflammation and to treat autoimmune diseases.

The differences between the instant application and USPN '787 is that USPN '787 claims an amino acid sequence of from 1-4 amino acid residues as opposed to the instant application which claims an amino acid sequence of from 1 to 5 amino acid residues.

However, the scope of the claims of the instant application and the claims of USPN '787 overlap because the claims of the instant application are broader and embrace the more limited compound claims of USPN '787.

Claim Rejections - 35 USC § 112

3. Claims 43-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

4. The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The claims are drawn to a method of treating an autoimmune disease in a mammal comprising administering an effective amount of the compound represented by the disclosed formula.

(2) The state of the prior art

The art recognizes numerous disorders characterized as autoimmune diseases. However, the art does not recognize that immunosuppressant agents produce the same effect on all immune responses thereby treating all autoimmune diseases in an equal manner.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the pharmaceutical and chemical art is high.

(5) The breadth of the claims

The claims are very broad and encompass treatment of numerous disorders characterized as "autoimmune diseases".

(6) The amount of direction or guidance presented

Applicant's specification does not appear to provide guidance for the treatment of autoimmune diseases which may encompass numerous disorders. The specification provides no guidance, in the way of written description, to enable one of ordinary skill in the art to use the invention commensurate in scope with the claims, which, as stated above, are broad and encompass numerous autoimmune disorders. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims

are capable of accomplishing the desired result." Applicant's specification does not set forth a representative number of examples of the claimed compounds which have immunosuppressive activity and which would be capable of treating various autoimmune disorders.

(7) The presence or absence of working examples

There are no working examples, in vivo or in vitro, in the specification relating to the treatment of autoimmune diseases.

(8) The quantity of experimentation necessary

Since (1) the claims embrace the treatment of many autoimmune disorders all of which may not respond equally to treatment with the claimed compounds and (2) since compound structure and activity for pharmaceutical use must be determined from case to case by painstaking experimental study, one of ordinary skill in the art would be burdened with undue experimentation to determine which compounds would have desired immunosuppressive activity as well as the autoimmune diseases which the claimed compounds would be effective in treating.

Conclusion

Claims 20-25, 28-32, 35-38, 41-46 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227.

The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM

April 16, 2003

Cybille Delacroix-Muirheid
Patent Examiner Group 1600